Remarks

Claims 1-23 are pending in the application and have all been rejected. Claim 1 has been amended to clarify that the stent is formed of the material recited in the preamble. No change in scope has been effected by this amendment.

Reconsideration of the Office Action mailed January 29, 2004, is respectfully requested.

Claim Rejections - 35 USC §102

Claims 1-23 have been rejected as anticipated by Stinson, US 6245103, (Stinson '103). The rejection is traversed.

Claims 1, 15, 17

The Office Action asserts:

> Stinson discloses in figs 1, 4 and col. 7, lines 54-67, col. 8, lines 1-17, a process for forming a stent having all the limitations of claims 1-2, 12,15,17-18 and 21-22, including: the process comprises the step of forming a tubular stent (10); the stent radially expands to produce an expanded diameter stent. Stinson discloses in figs 1, 4 and col. 7, lines 54-67, col. 8, lines 1-17, a process for forming a stent having all the limitations of claims 1-2, 12,15,17-18 and 21-22, including: the process comprises the step of forming a tubular stent (10); the stent radially expands to produce an expanded diameter stent. The step of annealing the expanded diameter stent that shrinks its diameter to a reduced diameter (see col. 12, lines 25-28). The process further comprises at least one time repeating steps b) and c) in sequence. The step of annealing the expanded diameter stent that shrinks its diameter to a reduced diameter (see col. 12, lines 25-28).

The Applicant does not agree.

In claims 1, 15, and 17, the stent is radially expanded in step b) ***and then*** the annealing step c) is performed. That is, these claims expressly recite a sequence. In order to anticipate applicant's claim 1, a prior art reference must teach the sequences recited.

The stent of the Stinson '103 patent is annealed before radial expansion occurs. The Stinson '103 sequence described at col. 5, lines 31-39:

> ... make the stent at a particular diameter (A), anneal the stent at a smaller diameter (B), and deploy the stent from a delivery system of diameter (C) whereby the stent will be "programmed" to self-expand to a desired implant diameter (D). The relationship between the diameters is A>B>D>C.

The Official Action refers to col. 12, lines 25-28 of the Stinson '103 patent for disclosure of an annealing step which reduces the stent diameter. This is so, but at this point in the process of Stinson '103, the stent has merely been braided, it has not been radially expanded. Therefore this example clearly fails to teach the sequence recited in claims 1, 15 and 17.

Stinson '103 does not pertain to a process in which an annealing step is performed on the stent after a radial expansion step. At least for this reason, claims 1, 15, 17, and each of their dependents are not anticipated by Stinson.

Claim 2, 15 and 18

Claims 2, 15 and 18 further recite that the radial expansion step b) and the annealing step c) are ***repeated*** at least once, ***in sequence.***

The Office Action asserts that the Stinson '103 "process further comprises at least one time repeating steps b) and c) in sequence."

Applicant disagrees. No citation has been provided in the Office Action for this assertion and nothing can be found in the Stinson '103 patent which even hints to a process involving two or more radial expansions followed each time by an annealing step.

(It should be noted that Stinson '103's discussion of annealing PLA monofilaments, at col. 3, lines 41 *et seq.*, is completely irrelevant to the annealing step recited in claims 2, 15 and 18.)

At least for the reasons given for claim 1, and further for these additional reasons, claims 2, 15, 17 and each of their dependents are not anticipated by Stinson '103.

Claim 3

Claim 3 recites the process of claim 1 wherein in step a) the stent is formed by molding. The Official Action states that Stinson '103 "discloses the stent is formed by molding or etching the polymer material (see col. 1, lines 43-66)." This is incorrect.

Stinson '103, column 1, lines 43-66, pertains to metal stents, not polymer material stents. No mention of molding or etching, much less of molding or etching a polymer stent, is found in this location. The polymer stents of the Stinson '103 invention are made by braiding polymer filaments, not by molding.

At least for the reasons given for claim 1, and further for the additional reasons that

Stinson '103 does not disclose a polymer stent formed by molding, claim 3 and each of its dependents are not anticipated by the Stinson '103 patent.

Claim 13

Claim 13 recites a thermoplastic polymer stent having a "hoopwise molecular orientation." The hoopwise molecular orientation is substantially circular, as shown in Fig. 7 and discussed at page 8, line 22 - page 9, line 5. The Stinson '103 stents are formed from longitudinally oriented fibers wound in a helical braid of crossing fibers. The orientation is not substantially circular. Even assuming that the molecular orientation in the Stinson '103 stent follows the longitudinal axis of the fibers, there is a substantial longitudinal component to each fiber winding. For this reason the Stinson '103 patent does not disclose a stent which anticipates claim 13 or claim 14 which depends therefrom.

Claim 21

Independent claim 21 recites an alternate process for forming a polymer stent which also includes an express sequence. In claim 21 a polymer tube is formed, radially expanded, annealed, ***and subsequently*** the stent is formed ***from the annealed tube***. That is, the stent pattern is provided ***after*** the tube has been both b) radially expanded and c) annealed at least one time. This may be accomplished, for instance, by machining or etching the tube after the steps b) and c) have been performed.

In the braided stent of the Stinson '103 patent, tube formation and stent pattern formation are the same step, *i.e.* braiding the tube over a mandrel. There is no teaching or suggestion of the process sequence as recited in claim 21.

The Office Action states that "Stinson discloses the stent is formed by molding or etching the polymer material (see col. 1, lines 43-66)." Again, this is incorrect. Stinson '103, column 1, lines 43-66, pertains to metal stents, not polymer material stents. No mention of molding or etching, much less of molding or etching a polymer stent, is found in this location.

At least for these reasons claim 21 and each of its dependents are not anticipated by the Stinson '103 patent.

Claim 22

Claim 22 depends from claim 21 and further recites that the steps b) and c) are repeated at least once before the step d) is performed, *i.e.* at least two radial expansion and at least two annealing steps are performed on the tube before the tube is provided with a stent form or pattern. The Stinson '103 patent does not employ the additional steps or the sequence recited in this claim. Consequently for this additional reason claim 22 is not anticipated by the Stinson '103 patent.

Claim Rejections - 35 USC §103

Claims 1, 13, 15, 17 and 21 have been rejected under 35 USC 103 (a) over Andrews et al. (US 6,156,254) in view of Lennard et al (US 4,911,165). The rejection is traversed.

The Office Action opens the rejection by stating:

> Andrews et al show in fig. 10, a process having all the limitations of claims 1, 13, 15, 17 and 21, including: the step of forming a tubular stent (10); the stent radially expands to produce an expanded diameter stent. However, Andrews et al do not disclose the step of annealing the expanded diameter stent that shrinks its diameter to a reduced diameter (see col. 12, lines 25-28).

Applicant does not agree.

Andrews et al shows a stent in Fig 10 "which is a coil of stainless steel" (col. 9 lines 19-24). Stainless steel is metal. Claims 1, 13, 15, 17 and 21 all pertain to processes or articles made of polymer, not metal. Andrews et al is irrelevant to the present application. A skilled person will not look to this document to find a polymer stent or a process for forming a polymer stent.

Even if the stainless steel stent of Andrews et al were relevant to the application, it does not show a stent formation process as asserted in the Office Action. Andrews et al pertains to a balloon formation process, not to a stent formation process. It teaches nothing about how the coil stent in Figure 10 is made.

The Office Action fails to indicate how the sequence recited in claims 1, 15, 17 or 21 are believed to be taught or suggested by Andrews et al. No such teaching exists.

The Office Action refers to "col 12, lines 25-28." This is not understood. The Andrews et al patent ends at the bottom of column 10.

Continuing with this rejection, the Office Action states:

> Lennard et al teach using polypropylene filaments then annealed in an oven and allowed to shrink from about certain percent of the original length (see col. 4, lines 55-65).
>
> It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify Andrews et al by adding polypropylene filaments then annealed in an oven and allowed to shrink as taught by Lennard et al et al in order to reduce the initial stretching and to allow the material to become constricted from heat or cold temperature. Furthermore, it will increase the final molecular orientation of the stent.

This is not understood.

Lennard et al pertains to surgical filament sutures. It doesn't pertain to stents. How is the examiner proposing to accomplish "adding" the filaments? Are the polypropylene fibers being used in some way as sutures? If not, why are suture filaments being used? Are they being used to form part of the Andrews et al stainless steel stent? If so what part?

The statement "in order to reduce the initial stretching and to allow the material to become constricted from heat or cold temperature," is understood to be an assertion of a motivation for the combination, but it is not understood what "initial stretching" is being referred to. Andrews et al doesn't describe an initial stretching of the Fig. 10 stent. Likewise what does "becoming constricted from heat or cold temperature" have anything to do with the Andrews et al stent? In Fig. 10 of Andrews et al, the stent is being implanted in the body where it is presumably at human body temperature. Still further, in what way does the addition of annealed polypropylene fibers going increase the final molecular orientation of a stainless steel stent?

In any case, as we have noted with respect to the Stinson '103 patent, use of annealed fibers to form a stent is irrelevant to the annealing steps recited in the various process claims. The annealing steps of the claims are all performed in a sequence and occur after a radial expansion of a formed stent, or before stent formation but after formation of the tube from which the stent will be cut or etched. Lennard et al has nothing to do with annealing at these process stages.

The applicant cannot see any motivation to combine the Andrews et al and Lennard et al patents for any purpose, and cannot see how any combination of these documents could produce the invention of any claim under examination. Withdrawal of the rejection under 35 USC §103 is respectfully requested.

Conclusion

The Stinson '103 patent does not anticipate any of claims 1-23. The anticipation rejection should be withdrawn. Neither Andrews et al, nor Lennard et al, pertain to polymer stents or to processes for forming same. They cannot be combined to render obvious a polymer stent or polymer stent forming process. Therefore the obviousness rejection of claims 1, 13, 15, 17 and 21 should also be withdrawn. The application is believed to be in condition for allowance. Early and favorable confirmation thereof is respectfully requested.

Respectfully submitted,

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